

Draft Workshop Agenda
Plant-Incorporated Protectant Experimental Use Permit: Process and Compliance
Crystal City Hilton, Arlington, Virginia
February 10 and 11, 2004
8:30 am - 5:00 pm

WORKSHOP PROGRAM - DAY ONE

- 8:30 - 9:00 Welcome and Purpose of the Workshop
 Welcome from EPA
 Background on scope, purpose, and desired outcomes of the workshop
 Agenda review and ground rules for the meeting
- 9:00 - 10:30 Panel Session: Goals related to activities under EUP
 Panel speakers will discuss their goals and mandates with regard to biotechnology research conducted under experimental use permits. The session will illuminate commonalities and differences between the Panel members
 Panel speakers will include:
 Janet Andersen, US EPA
 John Turner, USDA
 Russ Schneider, Monsanto
 Doug Gurian-Sherman, Agriculture and Biotechnology Consultant
 L. LaReesa Wolfenbarger, University of Nebraska at Omaha
- 10:00 - 10:15 Break
- 10:15 - 11:30 Regulatory Review Process of Field Testing
 USDA APHIS Notification and Permit Process - John Turner, USDA
 US EPA Experimental Use Permit Process - Mike Mendelsohn, USEPA
- 11:30 - 12:00 Introduction to brainstorming session on PIP EUP Issues
 Explanation of goals and format for the afternoon break-out sessions. Workshop participants will divide into four groups and consider each category in turn. The goal of these groups is to identify PIP EUP issues to be addressed in each category. During the Day 2 breakouts, participants will develop recommendations to address issues identified in this session. The categories are:
 - EUP application and decision process; content and data requirements
 - Regulatory terminology; definitions and standards
 - Containment and confinement; clarification of standards, strategies to achieve
 - Ensuring clear permit conditions and compliance with permit conditions
- 12:00 - 1:00 Lunch
- 1:00 - 2:20 Breakout sessions (40 minutes per session)

- 2:20 - 2:40 Break
- 2:40 - 4:00 Breakout sessions (40 minutes per session)
- 4:00 - 5:00 Summary of Day One, Preparation for Day Two
Volunteers from the break-out sessions will report back on the issues identified in each category.
Explanation of goals and format for Day 2 break-out sessions to identify remedies for issues identified in each category.

WORKSHOP PROGRAM - DAY TWO

- 8:30 - 8:45 Introduction - Day 2
Recap of goals and format for break-out sessions, and goals of afternoon panel discussions.
Concurrent sessions will be held on the four issue categories from Day 1.
Participants will be assigned to two topics total.
- 8:45 - 10:15 Breakout Sessions: Remedies and Recommendations
Rotation 1: Brainstorm possible approaches and recommendations to address the issues identified on Day 1.
- 10:15 - 10:30 Break
- 10:30 - 12:00 Breakout Sessions Remedies and Recommendations Continued
Rotation 2: Brainstorm possible approaches and recommendations to address the issues identified on Day 1.
- 12:00 - 1:00 Lunch
- 1:00 - 2:00 Recap of Morning Remedies and Recommendations
Representatives of each breakout group will summarize key recommendations
- 2:00 - 2:45 Panel Discussion: Coordination of USDA and EPA field testing programs
Panel speakers will include:
Phil Hutton, USEPA
John Turner, USDA
Natalie Hubbard, DuPont
Keith Pitts, Pew Initiative of Food and Biotechnology
- 2:45 - 3:00 Break
- 3:00 - 3:45 Panel Discussion: Balancing protection of proprietary information and public disclosure
Panel speakers will include:
Stan Abramson, Arent Fox Kintner Plotkin & Kahn

Peter Jenkins, Center for Food Safety

- 3:45 - 4:30 Panel Discussion: Compliance, why it matters and how it can be supported
Panel speakers will include:
Morven McLean, AgBios
Gregory Jaffe, Center for Science in the Public Interest
Terry Mitchell, Texas Department of Agriculture
- 4:30 - 5:00 Workshop Summary and Next Steps